

REMARKS/ARGUMENTS

Claim 61 has been amended to require the presence of a lipophilic compound solubilizing effective amount of at least one block amphiphilic copolymer, wherein the amphiphilic copolymer forms micelles on contact with a solvent consisting essentially of water. Support for this amendment exists throughout the present specification, particularly the examples.

Claims 41-52, 54-66, 68-82 and 84-88 are currently pending, although claims 41-52, 54-60, 81-82 and 86 have been withdrawn from consideration. Applicant currently intends to seek rejoinder of withdrawn claims, where appropriate, upon indication of allowable subject matter.

The Office Action rejected claims 61-66, 68-73, 75-80, 84, 87 and 88 under 35 U.S.C. § 103 as obvious over PCT patent application no. WO 01/12718 (“Seo”) in view of U.S. patent 6,994,846 (“L’Alloret”), claims 61, 73 and 74 under 35 U.S.C. § 103 as obvious over Seo and L’Alloret in view of U.S. patent application publication no. 2003/0027864 (“Guiramand”), and claims 61, 72 and 85 under 35 U.S.C. § 103 as obvious over Seo and L’Alloret in view of U.S. patent 5,246,693 (“Grollier”). In view of the following comments, Applicant respectfully requests reconsideration and withdrawal of these rejections.

The present invention relates to compositions comprising an aqueous phase in which a lipophilic compound is dissolved in the required amphiphilic polymer – that is, no need exists for first solubilizing the lipophilic compound in a solvent as well as a polymer, and then forming micelles by contacting the mixture with water. Rather, the present invention relates to combining the lipophilic compound and the required compound to solubilize the lipophilic compound in the required polymer (regardless of whether solvent is also present), and then contacting the lipophilic compound/required polymer mixture with water to form micelles. Stated another way, the present invention relates to new ways to solubilize a lipophilic using the unique polymers of the present invention. None of the applied art teaches or suggests this invention.

Regarding Seo, Seo discloses dissolving a polymer in a solvent (PEG, optionally including other organic solvents), and dissolving a drug in the polymer/PEG mixture. Thus, Seo teaches dissolving a drug in PEG – PEG is a vital, necessary component of Seo's dissolution mixtures. PEG also plays a vital role in forming micelles in Seo. Thus, Seo does not teach or suggest solubilizing a lipophilic compound in a solubilizing effective amount of at least one block amphiphilic copolymer and/or forming micelles by contacting the polymer with a solvent consisting essentially of water as required by present independent claim 61.

Similarly, Seo does not teach combining a lipophilic compound with at least one block amphiphilic copolymer, wherein the block copolymer is present in an amount effective to dissolve the at least one lipophilic compound. Rather, Seo teaches adding substantial amounts of solvent (PEG, organic solvent) in which the drug and polymer can be solubilized.

Indeed, Seo does not even teach or suggest the claimed polymers. Because Seo does not teach or suggest the required polymers, it necessarily cannot teach or suggest combining a lipophilic compound with such a non-disclosed polymer, or any benefits associated with such a hypothetical combination such as, for example, solubization of the lipophilic compound in the non-disclosed block amphiphilic copolymer.

The secondary references, L'Alloret, Guiramand, and Grollier, cannot compensate for these fatal deficiencies.

L'Alloret requires the presence of an ionic water-soluble hydrophilic polymer block, and states that synergistic gelation results from combining such an ionic hydrophilic block with other blocks (see, col. 4, line 2). In stark contrast, Seo discloses polymers having nonionic hydrophilic blocks (polyalkylene glycol) and a hydrophobic block selected from specified materials (see, page 6) which form could form a micelle. Thus, whereas L'Alloret requires the presence of an ionic hydrophilic block, Seo discloses polymers having nonionic hydrophilic blocks. Moreover, whereas L'Alloret states that synergistic gelation results from combining an ionic block with another block, Seo requires the presence of specific hydrophobic and hydrophilic components to form micelles. Given the specific teachings of each reference which, if followed, yield very different results (synergistic gelation vs. micelle), no motivation would have existed to combine different blocks from the two references with the expectation that a suitable product would result. Stated another way, given the requirements for different hydrophilic blocks in the two references, given the specificity with which Seo identifies acceptable hydrophobic blocks and given the vastly different products of the two references, nothing would have led one of ordinary skill in the art to substitute blocks from one reference in the other reference or to believe that such a substitution would have produced an acceptable product. Thus, the combination of L'Alloret and Seo cannot form the basis for a proper obviousness rejection.

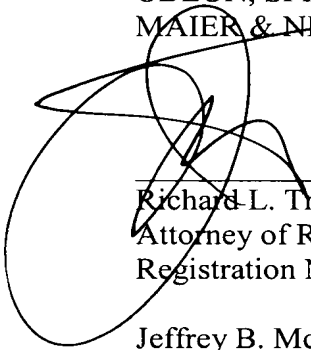
Guiramand, cited only for its disclosure of salicylic acid compounds, and Grollier, cited only for its disclosure related to specific oils, cannot compensate for Seo's fatal deficiencies either.

In view of the above, Applicant respectfully requests reconsideration and withdrawal of the rejections under 35 U.S.C. § 103.

Applicant believes that the present application is in condition for allowance. Prompt and favorable consideration is earnestly solicited.

Respectfully submitted,

OBLON, SPIVAK, McCLELLAND,
MAIER & NEUSTADT, P.C.



Richard L. Treanor
Attorney of Record
Registration No. 36,379

Jeffrey B. McIntyre
Registration No. 36,867

Customer Number

22850

Tel #: (703) 413-3000
Fax #: (703) 413-2220